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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/578,693	05/26/2000	Masaya Yamanouchi	20-4710P	9841

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EXAMINER	
COOK, LISA V	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/578,693	YAMANOUCHI ET AL.	
	Examiner	Art Unit	
	Lisa V. Cook	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,4,6,9,14-19 and 21-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,4,6,9,14-19 and 21-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Revocation of Finality

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action because the examiner inadvertently omitted claim 24 from the rejections of record has been considered and found persuasive. Therefore, the finality of that action is withdrawn.

2. Applicant's response to the Final Office Action mailed January 12, 2005 is acknowledged (paper filed 5/12/05). Currently claims 2, 4, 6, 9, 14-19, and 21-24 are currently pending and under examination.

Claim Status

3. Applicant's have requested clarification with respect to claim 24 because it was inadvertently not included in any of the rejections. Claim 24 should have been included in the rejection over Gorski et al. (Clinical Chemistry, 43, No.1, January 1997, pages 193-195) in view of Maatman et al. (Biochem. J. 1992, 288, pages 285-290) and Simon et al.(The Journal of Biological Chemistry, 272(16) 4/18/97, 10652-10663).

Although claim 24 was not recited in the heading of the rejection, the limitations of claim 24 were addressed in the body of the rejection and it does not change the obviousness of the instant invention (the rejections are maintained). Examiner apologizes for any inconvenience this may have caused Applicant.

NEW GROUNDS OF REJECTIONS

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

I. Claims 2, 4, 6, 16, 17, 18, 22, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gorski et al. (Clinical Chemistry, 43, No.1, January 1997, pages 193-195) in view of Maatman et al. (Biochem. J. 1992, 288, pages 285-290) and Simon et al.(The Journal of Biological Chemistry, 272(16) 4/18/97, 10652-10663).

Gorski et al. disclose a comparative study evaluating the increased concentration of fatty acid binding protein (FABP) concentrations in plasma samples of patients with chronic renal failure. Plasma FABP concentration was measured by a sensitive noncompetitive sandwich ELISA. PAGE 194 2nd column.

Plasma FABP concentration is shown to markedly increase in patients with chronic renal failure. Page 194, 3rd column. The findings suggest that the kidney plays a dominant role in the clearance of plasma FABP. Page 194 3rd column.

Gorski et al. differ from the instant invention in not specifically teaching the detection of liver-type fatty acid binding protein.

However, Maatman et al. identified the liver-type fatty acid binding protein utilized in the instant invention. Page 285, 1st column. This is supported by Applicants arguments (page 24 of the response filed 9/14/01 in paper #7). Maatmann et al. discloses liver-type fatty acid binding proteins and speculates that it is utilized in nephrotoxicity.

While, Simon et al. teach that the liver fatty acid binding protein functions to suppress expression in the proximal nephron (kidney). See abstract and page 10655.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the liver-type fatty acid binding protein as taught by Maatmann et al., having proven function is the kidney (nephron) as taught by Simon et al. to detect the specific kidney diseases relating to FABP in the method of Gorski et al. because Maatman et al. taught that "the liver-type FABP binds various ligands and may be involved in the renal excretion of exogenous and endogenous metabolites.

The liver-type FABP also binds some drugs and may in this way prevent nephrotxicity". Page 289, 2nd column 1st paragraph. While, Simon et al. demonstrated that the liver fatty acid binding protein [heptad repeat] mediate suppression in the stomach, liver, and kidney and represents a target for identifying transcription factors that regulate gene expression. See page 10662-1st column-last paragraph.

II. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gorski et al. (Clinical Chemistry, 43, No.1, January 1997, pages 193-195) in view of Maatman et al. (Biochem. J. 1992, 288, pages 285-290) and Simon et al.(The Journal of Biological Chemistry, 272(16) 4/18/97, 10652-10663) and further in view of Kimura et al. (Journal of Biological Chemistry, 3/25/91, Vol.266., No.9., pages 5963-5972).

See discussion of Gorski et al. in view of Maatman et al. and Simon et al. as set forth above.

Gorski et al. in view of Maatman et al. and Simon et al. differ from the instant invention in failing to teach that the liver-type FABP is found in the proximal tubule of the kidney and does not cross-react with a heart muscle-type fatty acid binding protein.

However, these characteristics of α_{2U}-globulin were already known in the prior art. Specifically Kimura et al. disclose that fatty acid-binding proteins found in the kidney could be distinguished according to their primary structure and histologic distribution. Two specific FABPs weighing 14 and 15.5 kDa were found in male rat kidney cytosol. The 14 kDa compound was identified as heart FABP and localized in the cytoplasm of the epithelia of the kidney distal tubules.

The 15.5 kDa compound was identified as a proteolytically modified form of α_{2U} – globulin (alpha 2u-globulin) and localized in the endosomes or lysosomes of kidney proximal tubules.

Gorski et al. in view of Maatman et al. and Simon et al. and in further view of Kimura et al. are all analogous art because they are from the same field of endeavor, both inventions teach methods involving FABP detection.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the antibody which would not cross-react with a muscle-type fatty acid binding protein as taught by Kimura et al., to detect the specific kidney FABP in the method of Gorski et al. in view of Maatman et al. and Simon et al. because such antibodies as taught by Kimura et al. are well known in the art.

A person of ordinary skill in the art would have had a reasonable expectation of success utilizing such antibody assays, because Kimura et al. had already taught that the kidney contained two different types of fatty acid binding proteins, one designated the heart-FABP and the other designated the kidney-FABP. (page 5964, Results).

One having ordinary skill in the art would have been motivated to distinguish between the two types by employing an antibody that would not cross react with the other type (heart-FABP/kidney distal tubules) in order to receive an accurate, more precise measure of the concentration of the FABP of interest (in this case kidney-FABP/ kidney proximal tubules).

III. Claims 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gorski et al. (Clinical Chemistry, 43, No.1, January 1997, pages 193-195) in view of Maatman et al. (Biochem. J. 1992, 288, pages 285-290) and Simon et al.(The Journal of Biological Chemistry, 272(16) 4/18/97, 10652-10663) and further in view of Galaske et al. (Pflugers Archives European Journal of Physiology, 1978, 375,3, 269-277-ABSTRACT ONLY).

Please see previous discussions of Gorski et al. in view of Maatman et al. and Simon et al.

Gorski et al. in view of Maatman et al. and Simon et al. differ from the instant invention in not teaching a detection system involving a chronic renal disease (anti-GMB-nephritis model) further monitoring specimen collection at various intervals.

Galaske et al. disclosed the glomerular filtration and tubular uptake of plasma proteins in the acute heterologus phase of an anti-GMB nephritis model. Injections of anti-glomerular-basement membrane serum (anti-GMB-serum) were evaluated in tubular reabsorption and tubular flow at various times. See abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a anti-GMB nephritis model as taught by Galaske et al., to detect kidney diseases via proteins in the method of Gorski et al. in view of Maatman et al. and Simon et al. because Galaske et al. disclose that such models existed allowing for protein detection in plasma and urine.

One of ordinary skill in the art would have been motivated to do this in order to detect renal disorders at the onset and follow the disease progression/regression.

IV. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gorski et al. (Clinical Chemistry, 43, No.1, January 1997, pages 193-195) in view of Maatman et al. (Biochem. J. 1992, 288, pages 285-290) and Simon et al.(The Journal of Biological Chemistry, 272(16) 4/18/97, 10652-10663) and further in view of Zuk et al. (U.S.Patent #4,281,061).

The teachings of over Gorski et al. in view of Maatman et al. and Simon et al. are set forth above. Although the reference teaches reagents for examining kidney disease, the references fail to teach the assay as a kit.

However, Zuk et al. (4,281,061) teach that "as a matter of convenience the reagents [of an immunoassay] can be provided as kits, where the reagents are in predetermined ratios, so as to substantially optimize the sensitivity of the assay in the range of interest" (column 22, lines 63-66).

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to take the kidney disease detection assay as taught by over Gorski et al. in view of Maatman et al. and Simon et al. and format them into a kit because Zuk et al. teach that it is convenient to do so and one can enhance sensitivity of a method by providing reagents as a kit. Further, the reagents in a kit are available in pre-measured amounts, which eliminates the variability that can occur when performing the assay.

Response to Arguments

5. Applicant's arguments filed May 12, 2005 have been fully considered but they are not persuasive.

The Declaration under 37 CFR 1.132 filed May 12, 2005 is insufficient to overcome the rejections of claims 2, 4, 6, 9, 14-19, and 21-24 based upon the rejections as set forth in the last Office action because: The declaration argues Long felt need. It states that the claimed subject matter solved a problem that was long standing in the art. However, there is no showing that others of ordinary skill in the art were working on the problem and if so, for how long. In addition, there is no evidence that if persons skilled in the art who were presumably working on the problem knew of the teachings of the above cited references, they would still be unable to solve the problem. See MPEP §716.04.

Attorney's arguments of unexpected results cannot take the place of evidence in the record. *In re DeBlauwe,* 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed.Cir.1984).

Applicant contends that Gorski discloses a study, which details the concentrations of H-FABP with respect to chronic renal failure. Thus, there is no motivation to replace the H-FABP of Gorski with the L-FABP of Maatman and Simon because H-FABP and L-FABP are not interchangeable (not functionally equivalent). This argument was carefully considered but not found persuasive because although H-FABP and L-FABP are not functionally equivalent they are similarly found in the kidney. The art teaches that only H-FABP and L-FABP are found in the kidney (See Maatman: esp, page 765- Kidney type A is identical to L-FABP and Kidney type B is identical H-FABP) and the prior art also teaches that H-FABP and L-FABP are similar in structure/ 20-35% homologous (See Veerkamp: esp. page 4 2nd column). Therefore, it remains examiners position that H-FABP and L-FABP are obvious substitutes in assessments for kidney disorders.

Applicant also argues that Gorski, Maatman, or Simon do not suggest or disclose the diagnosis of kindney disease in a human using L-FABP. This argument was carefully considered but not found persuasive because the test for obviousness is not whether the features of one reference may be bodily incorporated into the other to produce the claimed subject matter but simply what the combination of references makes obvious to one of ordinary skill in the pertinent art. See, In re Bent, 52 CCPA 850, 144 USPQ 28 (1964); In re Nievelt, 179 USPQ 224 (CCPA 1973).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, Applicant contends that Gorski et al. teach methods of measuring plasma levels of H-FABP in kidney/renal diseases. While, Maatman et al. and Simon merely speculate as to L-FABPs role in kidney/renal disorders. Therefore there is no motivation to combine Gorski et al., Maatman et al., and Simon et al. This argument was not found persuasive because Maatman et al. disclose that "Based on the RT-PCR and hybridization results, the content of the mRNAs of the liver and heart FABP types do not differ markedly in kidneys of male and female rats". See page 289 1st column and figure 6. Therefore, one of ordinary skill in the art at the time of applicant's invention would have been motivated to replace the H-FABP of Gorski et al. with the L-FABP taught by Maatman et al. and Simon et al. because the two types of FABP (heart and liver) were functional equivalents (do not differ markedly).

Applicant argues that the examiner has applied an "obvious to try standard." An "obvious to try" standard is deemed impermissible in two situations: 1) where the prior art gives no indication as to which of numerous parameters are critical, or give no indication as to which of many possible choices is likely to be successful; and 2) where the prior art gives only general guidance with respect to the form of the invention, but not how to achieve it in new areas of technology or in fields of experimentation which are only seemingly promising. In re O'Farrell, 853 F.2d 894, 7 USPQ 2d 1673, 1681 (Fed Cir 1988).

Because Maatman et al. give specific information regarding the similarities of H-FABP and L-FABP, the rejections are not mere "obvious to try" but the obvious use of equivalents. See page 289 1st column and figure 6.

Applicants contend that Gorski et al. teaches away from the use of FABP as a marker for kidney disease. However, Gorski et al. disclose that their data was the first to show that plasma FABP concentration is markedly increased in patients with chronic renal failure. . . . See page 194 3rd column 2nd paragraph.

In response to the argument that Gorski et al. is focused on heart-type FABP as a marker for myocardial infarction, further teaching away from the instant invention because heart type FABP and liver-type FABP are different structures. This argument was carefully considered but not found persuasive because Gorski et al. is cited in combination with two other references, which must be considered in combination. Although Gorski et al. do not specifically detect liver-type FABP the structure is taught to be relevant in kidney disorders in the references of Maatman et al. and Simon et al.

While a deficiency in a reference may overcome a rejection under 35 USC 103, a reference is not overcome by pointing out that a reference lacks a teaching for which other references are relied. In re Lyons, 364 F2d 1005, 150 USPQ 741, 746 (CCPA 1966).

Gorski et al. further teaches not only myocardial infarction but is also concerned with chronic renal failure. This is supported on page 194, 1st paragraph "we studied plasma FABP and myoglobin in patients with chronic renal failure" and page 194 3rd paragraph "The present data are the first to show plasma FABP concentration is markedly increased in patients with chronic renal failure and normal heart function, similar to that found for myoglobin." "These findings suggest that the kidney plays a more dominant role in the clearance of plasma FABP than of myoglobin."

Further, the reference of Gorski et al. taught that plasma FABP concentration is markedly increased in patients with chronic renal failure and normal heart function. See page 194 3rd column 2nd paragraph. The similarity between H-FABP and L-FABP is taught by Maatman et al. See page 289 1st column and figure 6. Thus elevation of H-FABP or its functional equivalent L-FABP in renal disease is obvious and supports the clinical findings of Kamijo et al.

Applicant argues that Maatman et al. merely speculate that L-FABP may prevent nephrotoxicity, however the function of L-FABP does not shed light on the normal or abnormal levels of FABP in a human specimen. This argument was carefully considered but not found persuasive because Maatman et al. was cited in combination with Gorski et al. Maatman et al. disclose the relevance of L-FABP in the liver (function) and teach the similarities between L-FABP and H-FABP. Gorski et al. teach FABP levels in normal and abnormal human specimens having renal disease. See Gorski et al. page 194, 1st and 3rd columns.

Applicant's arguments directed to creatine, urea, and myoglobin comparison are not found persuasive because these compounds are not recited in the instant claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claims and references are cited with respect to the utility of L-FABP in kidney or renal disease.

Applicant argues that no correlation between the known markers for kidney disease (creatinine and urea) and FABP was provided therefore, the skilled artisan would not be motivated to measure FABPs in kidney disease. This argument was carefully considered but not found persuasive because Gorski et al. show correlated increase over controls of measured FABP, creatinine, and urea in patients with chronic renal failure. See Table 1 on page 194.

In response to applicant's argument based upon the age (far apart) of the references, contentions that the reference patents are old are not impressive absent a showing that the art tried and failed to solve the same problem notwithstanding its presumed knowledge of the references. See *In re Wright*, 569 F.2d 1124, 193 USPQ 332 (CCPA 1977).

Applicant argues that Simon et al. do not make any connection between an increased in L-FABP protein and kidney disease. This argument was carefully considered but not found persuasive because Simon et al. was merely cited to further support a function of L-FABP in the kidney. See abstract and page 10655. Where, Simon et al. teach that the liver fatty acid binding protein functions to suppress expression in the proximal nephron (kidney). Simon et al. are cited in combination with in combination with Gorski et al. Gorski et al. teach increased levels of FABP levels renal disease (kidney). See Gorski et al. page 194, 1st and 3rd columns. While, Maatman et al. disclose the relevance of L-FABP in the liver (function) and teach the similarities between L-FABP and H-FABP. While a deficiency in a reference may overcome a rejection under 35 USC 103, a reference is not overcome by pointing out that a reference lacks a teaching for which other references are relied. In re Lyons, 364 F2d 1005, 150 USPQ 741, 746 (CCPA 1966).

Applicant contends that Gorski et al. only use H-FABP as a marker for myocardial infarction and do not suggest FABP as a marker for any other disease namely kidney disease. This argument was carefully considered but not found persuasive because Gorski et al. discloses plasma FABP increase in patients with chronic renal failure and normal heart function. See page 194 3rd column 2nd paragraph.

Applicant contends that Gorski et al. although Gorski et al. show that plasma FABP (H-FABP) is increased in patients with renal failure, this was only done to prevent an erroneous interpretation in the diagnosis of myocardial infarction in patients with renal insufficiency. This argument was carefully considered but not found persuasive because there is no requirement that the prior art must suggest that the claimed product (FABP) will have the same or similar utility as that discovered by applicant in order to support a legal conclusion of obviousness. *In re Dillon*, 919 F2d 688, 696, 16 USPQ 2d 1897, 1904 (Fed Cir 1990) (in banc), cert. denied, 111 S. Ct. 1682 (1991). An obvious rejection is proper so long as the prior art suggests a reason or provides motivation; even where the reason or motivation is different from that discovered by applicant.

With respect to the remaining rejections applicant has only directed their arguments against Gorski, Maatman, and Simon. The arguments have been addressed above and all rejections are maintained.

6. For reasons aforementioned, no claims are allowed.

7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to Group TC 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see httpr//pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lisa V. Cook
Art Unit 1641
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September 7, 2005

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09/10/05